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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,267	12/31/2001	Sidney Pestka	PBLI-P01-010	9576

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EXAMINER	
PRYOR, ALTON NATHANIEL	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/040,267	PESTKA, SIDNEY	
	Examiner	Art Unit	
	Alton N. Pryor	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *12 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *26-28,31-58,67-70,73 and 74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *27 and 57* is/are allowed.

6)☐ Claim(s) *26,28,31-56,58,67-70,73 and 74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

I. Upon further consideration, a new ground(s) of rejection is made in view of the broadness of the claimed subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims *26,28,31-56,58,67-70,73 and 74* are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1) Nature of invention.

2) State of prior art.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

4) Level of predictability in the art.

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7) Breadth of claims.

8) Level of ordinary skill in the art.

See below:

1) Nature of the invention.

The nature of the invention is to a sustained release formulation biopolymer prepared by exposing the biopolymer in aqueous solution to an organic solvent. In addition, the biopolymer, if stabilized, is stabilized by monovalent cation.

2) State of the prior art and the predictability or lack thereof in the art.

The state of the prior art is to sustained release interferon (biopolymer) prepared by exposing interferon in an aqueous carrier and then drying of the interferon (biopolymer) prior to exposure to an organic solvent. Interferon is stabilized by Zn+2 divalent cation (USPN 5711968). Whereas, instant sustained release interferon (biopolymer) is prepared by exposing interferon (biopolymer) in aqueous medium to organic solvent in order to produce a sustained release biopolymer. Instant claims that biopolymer can be stabilized by monovalent cations.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The quantity of experimentation needed is undue experimentation. One of ordinary skill in the art would need to 1) collect a number of biopolymers, 2) determine which biopolymers can be formulated as aqueous solutions, 3) collect a number of organic solvents 4) expose the biopolymer in aqueous solution to the organic solvent and 4) determine which combinations (i.e. which aqueous polymers when combined which organic solvents) would yield sustained release polymers optionally stabilized by monovalent cations.

6) Existence of working examples.

Working examples are found on pages 13-26 wherein sustained release formulation have been formulated from combinations of aqueous solutions albumin (biopolymer) and interferon (biopolymer) with organic solvents such as propanol and butanol. Applicant's claims are not commensurate in scope with the examples provided in the specification.

7) Breadth of claims.

Claims are extremely broad due to the vast number of possible biopolymers and organic solvents encompassed by the instant invention.

8) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. Due to the large number of biopolymers and large number of organic solvents as well as due to the unpredictability in the pharmaceutical art as to which combinations would yield a sustained released biopolymer.

Hence, the specification fails to provide sufficient support of the use of numerous biopolymers (in aqueous solution) when exposed to numerous organic solvents result in sustained released biopolymers. As a result necessitating one of ordinary skill in the art to perform an exhaustive search to determine which aqueous solutions of biopolymers form a sustained release biopolymer when exposed to organic solvent.

Genentec Inc. V. *Novo Nordisk A/S* (CAFC) 42 USPQ 2D 1001, states that:

"a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of ordinary skill in the art

would have to engage in undue experimentation which involve an artisan to 1) collect a number of biopolymers, 2) determine which biopolymers can be formulated as aqueous solution, 3) collect a number of organic solvents 4) expose the biopolymer in aqueous solution to the organic solvent and 4) determine which combinations (i.e. which aqueous polymers when combined which organic solvents) would yield monovalent sustained release polymers, with no reasonable expectation of success.

Claims *26,28,31-56,58,67-70,73 and 74* rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. A teaching that "if the biopolymer is stabilized by a cation, the cation is a monovalent cation" is new matter.

II. Addressing Applicant's Amendment / Argument

Applicant's arguments, see paper, filed 6/12/06, with respect to the rejection(s) of claim(s) under 35 USC 102(b)/103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. Rejection of claims under 35 USC 102(b) / 103(a) as being obvious over Tracey et al (USPN 5711968) will not be maintained in light of amendment filed 6/12/06. The prior art does teach or suggest the exposure of interferon in an aqueous medium to organic solvent in order to produce sustained release monovalent stabilized interferon (biopolymer). It is important to note that the rejection with respect to Tracey will be reapplied if the monovalent cation is removed from the claims.

Election Status

Elected invention comprising a monovalent stabilized interferon and propanol is not allowable. The prior art does teach or suggest the exposure of monovalent stabilized interferon (biopolymer) in an aqueous medium to organic solvent in order to produce a sustained release biopolymer.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alton Pryor
Primary Examiner
AU 1616